IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN THE APPLICATION OF:

Appellant	:	Scarguard Labs, LLC	
SERIAL NO.	:	10/829,315	ART UNIT: 1615
FILED	:	04-21-2004	EXAMINER: Sheikh, Humera N .
Attorney Docket #:		SDF 04-15	CONFIRMATION NO.: 5670

First named inventor: Joel R. Studin
Title of Invention: Method and composition for the treatment of scars

BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Under the provisions of 37 C.F.R. § 41.37, this Appeal Brief is being filed together with an electronic payment in the amount of $270.00, covering the 37 C.F.R. § 41.20(b)(2) appeal fee for a small entity. An appropriate extension fee is also attached extending the date to file the Brief of Appeal to August 7, 2009.

I. REAL PARTY IN INTEREST

The real party in interest is Scarguard Labs, LLC, the assignee of record. The real party of interest is hereinafter sometimes referred to as the "Applicant".

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals and/or interferences relating to this application.

III. STATUS OF CLAIMS

Of Claims 1-54 originally filed, claims 1-16 and 30-54 were cancelled by Preliminary Amendment on April 21, 2004. Claims 26-29 were subsequently cancelled by Amendment on April 13, 2007 under 37 C.F.R. 1.111. Claims 17-25 are pending of which claims 17 and 19 are independent claims. Claim 18 depends on claim 17; and claims 20-25 depend directly or indirectly on claim 19.

IV. STATUS OF AMENDMENTS

A response without amendment was filed March 9, 2009, subsequent to the final rejection. There are no related Appeals or Interferences.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 17 is directed to a method claim for treating immunological skin disorders (see, *e.g.*, see Applicant's specification at page 8, lines 20-23; page 11, lines 21-23; page 12, lines 5-8) comprising applying onto an area of skin (see, e.g., Applicant's specification at page 22, lines 10-11; and claim 1 as originally filed) affected by said skin disorder a fluid, film-forming carrier having contained therein a steroid (see, e.g., Applicant's specification page 9, lines 23 continuing to line 3 on page 10), and hardening the carrier into a tangible, membrane (see, *e.g.*, Applicant's specification at page 14, lines 5-6) juxtaposed to said affected area (see, e.g., Applicant's specification at page 9, line 23 continuing to line 3 on page 10), wherein said film-forming carrier is nitrocellulose (see, *.e.g.*, Applicant's specification at page 13, lines 17-24).

Dependent claim 18 is drawn to the method of claim 17, wherein said skin disorder is eczema, psoriasis, or atopic dermatitis (see, *e.g.*, Applicant's specification at page 20, lines 25-26).

Independent claim 19 is directed to a composition for treating adverse skin conditions (see, *e.g.,* Applicant's specification at page 20, lines 23-25) comprising a fluid, film-forming carrier and an active ingredient comprising a topically active steroid or, a silicone-gel or mixture thereof (see, *e.g.,* Applicant's specification at page 21, lines 3-6), said carrier capable of hardening into a tangible membrane (see, *e.g.,* Applicant's specification at page 21, lines 7-8), wherein said film-forming carrier is nitrocellulose (see, *.e.g.,* Applicant's specification at page 13, lines 17-24).

Dependent claim 20 is drawn to the composition of claim 19, wherein said active ingredient is a topically active steroid comprising at least one corticosteroid or a pharmaceutically acceptable salt thereof (see, *e.g.,* Applicant's specification at page 17, lines 3-7).

Dependent claim 21 is drawn to the composition of claim 19, wherein said active ingredient is a silicone-gel (see, *e.g.,* Applicant's specification at page 10, line 5).

Dependent claim 22 is drawn to the composition of claim 21, wherein said silicone-gel is phenyltrimethicone (see, *e.g.,* Applicant's specification at page 19, lines 19-22).

Dependent claim 23 is drawn to the composition of claim 19, wherein said active ingredient comprises a mixture of said steroid and silicone-gel (see, *e.g.,* Applicant's specification at page 21, lines 3-6).

Dependent claim 24 is drawn to the composition of claim 19, wherein said active ingredient further contains a vitamin (see, *e.g.,* Applicant's specification at page 9, line 5).

Dependent claim 25 is drawn to the composition of claim 23, wherein said active ingredient comprises a mixture of said topical steroid, a silicone-gel, and optionally, vitamin E (see, *e.g.,* Applicant's specification at page 10, lines 14-20).

VI. GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL

(1) Claims 17-21, 23 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Youssefyeh, et al. (U.S. 5,968,519) in view of Mantelle, et al. (U.S. 6,562,363).

(2) Claims 17-21, 23 and 25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh et al. (U.S. Pat. No. 5,968,519) in view of Brandt et al. (U.S. Pat. No. 6,627,216).

(3) Claims 22 and 24 stand rejected under 35 U.S.C. Section 103(a) as being unpatentable over Youssefyeh, et al. (U.S. 5,968,519) in view of Herb et al. (U.S. Pat. No. 5,534,246).

(4) Claims 17-21, 23 and 25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle, et al. (U.S. 5,446,070) in view of Mantelle, et al. (U.S. 6,562,363).

(5) Claims 17-21, 23 and 25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Brandt et al. (U.S. Pat. No. 6,627,216).

(6) Claims 22 and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Herb et al. (U.S. Pat. No. 5,534,246).

VII. ARGUMENTS

A1. Rejections under 35 U.S.C. § 103(a)

(1) Rejection of Claims 17-21, 23 and 25 under 35 U.S.C. § 103 (Re: Youssefyeh in view of Mantelle '363)

Claims 17-21, 23 and 25 stand rejected under 35 U.S.C. Section 103(a) as being unpatentable over Youssefyeh, et al. (U.S. 5,968,519, hereinafter "Youssefyeh") in view of Mantelle, et al. (U.S. 6,562,363, hereinafter "Mantelle '363"). (See paragraph 4 on page 2 of the Final Office Action dated January 23, 2009, hereinafter the "Final Office Action".)

Independent Claim 17

Applicant respectfully submits that it is well settled that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. Applicant respectfully asserts that Youssefyeh does not disclose or suggest all the claim limitations presently claimed, and Applicant submitted a Rule 131 Declaration to overcome Mantelle '363; in addition, the Applicant submitted a Rule 132 Declaration in support of the nonobvious nature of the claimed invention. The Rule 131 and 132 Declarations were filed in accordance with 37 C.F.R. 1.131 and 1.132, respectively.

With regard to Youssefyeh, the Examiner acknowledged that "Youssefyeh do not teach that the film-forming carrier is nitrocellulose." (Final Office Action at page 4, lines 16-17). In seeking to overcome the deficiency in Youssefyeh, the Examiner relied upon Mantelle '363. Applicant respectfully submits that the Rule 131 Declaration and Exhibit A thereof of Joel Studin (see Appendix IX) overcomes the Mantelle '363 reference thereby rendering the Examiner's obvious argument irrelevant. In the Rule 131 Declaration, Joel Studin directed Bryce Labs to prepare a composition for treating scars, eczema and psoriasis, containing a steroid (hydrocortisone acetate) in a film-forming carrier (flexible collodion), and apply the formulation to skin. Flexible collodion contains nitrocellulose. This was done prior to December 3, 1996. See Declaration at section 5. In as much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier for treating scars, eczema, psoriasis and applied the formulation to skin), prior to the earliest effective date of the Mantelle '363 reference (September 26, 1997), Mantelle '363 is no longer an effective reference against the invention as claimed.

As a general matter, the Examiner's dismissal of the Rule 131 Declaration was improper. Applicant's Rule 131 Declaration showing that the claimed film-forming carrier with

hydrocortisone for applying onto a skin for the treatment of scars, psoriasis, and eczema, was reduced to practice prior to the filing date of both Mantelle '363 and the primary reference Youssefyeh. The Examiner dismissed this showing by stating that the declaration does not show establishment of the claimed invention. See Final Office Action at page 11, third paragraph. However, the Rule 131 Declaration clearly states, prior to the filing date of both Mantelle '363 and the primary reference to Youssefyeh, that the composition was tested for the purpose of treating scars, eczema, and psoriasis, as stated in Section 5 of the Rule 131 Declaration (see Evidence Appendix IX). Accordingly, it is believed that the Rule 131 Declaration demonstrates reduction to practice of the claimed invention prior to the applied references. Importantly, the Rule 131 Declaration shows reduction to practice of applying onto skin a composition of a steroid on a nitrocellulose prior to the effective date of Mantelle '363. The Rule 131 Declaration only needs to show that part of the invention disclosed in the applied reference. Accordingly, if the Rule 131 Declaration is not sufficient to overcome Youssefyeh, it most certainly is effective for predating Mantelle '363.

In the Advisory Action dated April 3, 2009, the Examiner again dismisses the Rule 131 Declaration by stating that the "comprising" claim language does not exclude any additional celluloses disclosed by the art. This argument is not at all understood inasmuch as the claimed method is directed to the application of nitrocellulose. Applicant has shown by a Rule 131 Declaration that prior to the effective date of both applied references, Applicant has applied a composition comprising nitrocellulose and an active as a film onto skin for the purpose of treating scars, eczema, and psoriasis. This ends the matter. That the other references teach celluloses other than nitrocellulose is irrelevant. The claimed invention is directed to application of nitrocellulose.

As will be explained further below, Applicant has further shown the non-equivalence between nitrocellulose and other celluloses as a film-forming carrier for active ingredients onto skin.

Applicant has also submitted a Rule 132 Declaration of Joel Studin (copy of the Rule 132 Declaration is found attached hereto in Appendix IX). The Rule 132 Declaration of Joel Studin shows a comparison of transdermal effectiveness of various possible film-forming carriers for delivering topical treatments such as corticosteroids. According to the Rule 132 Declaration, Nitrocellulose (Flexible Collodion) had the highest blanching test score of 141, and nitrocellulose (flexible collodion/xanthan gum) has the second highest test score with a 59. Again, the higher the score, the higher the degree of blanching, and thus, the highest degree of transdermal transmission of the active agent (hydrocortisone) tested. See the Rule 132 Declaration originally submitted April 24, 2008, at paragraph 8; see also Exhibit A at page 6; the Rule 132 Declaration and Exhibit A are attached hereto in Appendix IX. The Honorable Board of Appeals is kindly directed to the bottom of page 6 of Exhibit A of the Rule 132 Declaration, which states, "[m]ost carriers showed very poor transdermal transmission of the active. Nitrocellulose however, showed a very strong transmission in our formulation... [i]t is our suggestion that you continue the development of your products using the nitrocellulose base that you suggested." Therefore, Applicant respectfully asserts that use of nitrocellulose as the film-forming carrier shows a superior level of blanching of hydrocortisone into the skin when compared to other film-forming cellulose carriers. Accordingly, the substitution of nitrocellulose film of the secondary reference (Mantelle '363), for those cellulose films of the primary reference Youssefyeh, yields unexpected results as shown by the Rule 132 Declaration. This is the antithesis of obviousness!

In the Advisory Action, the Examiner again dismisses the Rule 132 Declaration stating that the instant "comprising" claim language permits the presence of additional ingredients, including

the addition of celluloses of Mantelle. Again, this argument is not at all understood inasmuch as the claimed method is directed to a film-former comprising nitrocellulose. Applicant has shown the non-equivalence between nitrocellulose and other celluloses disclosed in Mantelle. Mantelle does not specifically disclose a composition comprising a mixture of nitrocellulose and other celluloses. Mantelle lists numerous polymers which can be included in his bio-adhesive materials, including substituted and unsubstituted celluloses, which are set forth in column 5, lines 51-57 of the patent. In the Rule 132 Declaration, Applicant has shown the vast superiority of nitrocellulose relative to other substituted cellulose materials, which are listed in Mantelle.

The Examiner also states in the Advisory Action that a method for improving or increasing transdermal penetration is not being claimed. While the claimed method does not recite transdermally penetrating an active into the skin and into the blood system of a patient, clearly, the treatment of a skin disease with an active agent denotes that the active agent must transmit through the carrier and contact and penetrate the area of the skin in which the disease is present. The Honorable Board of Appeals is invited to the instant specification at page 7, lines 11-19, where is it is stated that the composition of the invention "forms a solid, tangible film as above described which maintains the steroid active ingredient juxtaposed to the wound or scar tissue, and provides an advantageous and continuous healing effect of the steroid. As previously disclosed, adjuvants typically used for topical compositions can be added, including solvents, penetration enhancers, (underlining added), emollients,... as long as such addition does not adversely interfere with the effectiveness of the steroid." Further, the specification at page 17, last line, through page 18 line 3, states "the film-forming carrier which forms a solid film on the affected area and provides a base from which the actives can act upon the healed wound or the scar tissue and provide the desired improvement."

At page 21, lines 20-26, it is also stated that the "film-forming carriers of this invention can contain such medicaments such as chemotherapeutic agents, which can be applied to the skin to topically treat skin cancers or form a reservoir, which when applied to the skin, can transdermally direct the medicaments to the underlying tissue and the blood stream." Clearly, the Rule 132 Declaration shows that the effectiveness of nitrocellulose as a film-forming carrier for medicaments for application of the medicaments to the skin or underlying tissue are vastly superior to other celluloses described in the applied references.

Regarding the Rule 132 Declaration, the Examiner further stated that Exhibit A shows no data that would represent the generic concept claimed. Thus, the Examiner states the claims are directed to a steroid whereas only a single corticosteroid has been presented. Also, the amount of the active ingredient compared in Applicant's data has not been claimed, nor are the present claims restricted to the time intervals of the Exhibit. The Examiner's comments do not fairly represent the showing of the 132 Declaration. All Applicant attempted to show was how various types of cellulose carriers would transmit an active ingredient, such as a steroid, onto the skin. Thus, numerous celluloses including methylcellulose, hydroxy methylcellulose, nitrocellulose, hydroxyethyl cellulose, and cellulose acetate were all tested with the same steroid, the same amount of steroid, and for the same time periods to determine whether the active ingredient could be transferred to the skin. Applicant clearly shows that the nitrocellulose had the best transdermal effectiveness. There is no reason to expect that other steroids would be different, nor is it reasonable for Applicant to put in a time limit. Clearly a 1-4 hour time limit is sufficient enough to test whether a carrier can allow an active ingredient to be incorporated into the skin. It was the carriers which were the components being tested for transmitting an active ingredient, and it is likely that any active would yield the same results, and certainly any type of steroid would yield the same results as

those shown. Accordingly, it is believed that the Rule 132 Declaration is sufficient to show that the film-forming carrier of nitrocellulose is an improved carrier of active components to the skin over other cellulose film carriers.

Independent Claim 19

With regard to claim 19 (and claims 20-25 which depend directly or indirectly on claim 19), claim 19 has been amended to recite, "[a] composition for treating adverse skin conditions comprising a fluid, film-forming carrier and an active ingredient comprising a topically active steroid or, a silicone-gel or mixture thereof, said carrier capable of hardening to a tangible member, wherein said film-forming carrier is nitrocellulose."

Applicant respectfully refers to the Rule 131 Declaration of Joel Studin, attached herewith (Appendix IX). As shown by the Rule 131 Declaration, Joel Studin invented the presently claimed invention prior to the earliest priority dates of Youssefyeh (December 3, 1996) and Mantelle '363 (September 26, 1997). According to the Declaration, Joel Studin directed Bryce Labs to prepare a composition for treating scars, eczema and psoriasis, containing a steroid (hydrocortisone acetate) in a film-forming carrier (flexible collodion), and apply the formulation to skin, prior to December 3, 1996. See the Rule 131 Declaration at section 5. In as much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), prior to the earliest effective date of both Youssefyeh (December 3, 1996) and the Mantelle '363 reference (September 26, 1997), Youssefyeh and Mantelle '363 are no longer effective references against the invention as claimed.

As noted previously, the Examiner's dismissal of the Rule 131 Declaration was improper. Applicant's Rule 131 Declaration shows that the claimed composition comprising a film-forming carrier with a steroid for applying onto skin was reduced to practice prior to the effective filing

dates of both Mantelle '363 and the primary reference to Youssefyeh. The Examiner dismissed this showing by stating that the declaration does not show establishment of the claimed invention. See Final Office Action at page 11, third paragraph. However, claims 19-25 are directed to a composition. The declaration clearly shows a composition containing nitrocellulose and a steroid. Further, the Rule 131 Declaration clearly states, prior to the filing date of both Mantelle '363 and the primary reference to Youssefyeh, that the composition tested was explicitly for the purpose for treating scars, eczema, and psoriasis as stated in Section 5 or the Rule 131 Declaration (see Evidence Appendix IX). Inasmuch as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), it is believed that the Rule 131 Declaration demonstrates reduction to practice of the claimed invention prior to the applied references.

More importantly, Applicant does not have to show the reduction to practice of the entire claimed invention prior to the references, but only needs to provide evidence that Applicant possessed so much of the invention as is shown in the reference. Clearly, Applicant has shown that a composition comprising an active such as a steroid in a nitrocellulose film carrier was practiced prior to the filing of Mantelle, et al. The Declaration under Rule 131 is also clearly sufficient to show a composition of a film-former and active applied to skin for the purpose of treating scars, eczema, and psoriasis prior to Youssefyeh.

The Declaration submitted under Rule 132 discussed above is also applicable to show the unexpected properties of the claimed composition. Those arguments presented above with respect to the effectiveness of the Rule 132 Declaration to show the unobviousness of claims 17 and 18 are just as relevant to the composition claims 19-25. The superiority of nitrocellulose as a carrier for a steroid is not suggested in the applied references.

With specific regard to dependent claim 21, which recites that the active ingredient is a silicone-gel, the primary reference of Youssefyeh teaches the addition of silicones at column 15, lines 43-46. However, the addition of silicones is in the ointments, pastes, creams, or gels of the reference. There is absolutely no suggestion that such materials can be incorporated in a film-forming material as claimed.

Accordingly, it is believed that the rejection of the claims over the combination of Youssefyeh and Mantelle '363 is improper and should be reversed.

(2) Rejection of Claims 17-21, 23 and 25 under 35 U.S.C. § 103 (Re: Youssefyeh in view of Brandt)

Claims 17-21, 23 and 25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh, et al. (US. 5,968,519, "Youssefyeh") in view of Brandt, et al. (U.S. 6,627,216, "Brandt").

Applicant respectfully asserts that Youssefyeh does not disclose or suggest all the claim limitations presently claimed, and Applicant submits herewith the Rule 131 and Rule 132 Declarations to overcome the combination of Youssefyeh and Brandt.

Independent claim 17

Claim 17 is directed to, "[a] method of treating immunological skin disorders comprising applying onto an area of skin affected by said skin disorder a fluid, film-forming carrier having contained therein a steroid, and hardening the carrier into a tangible, member juxtaposed to said affected area, wherein said film-forming carrier is nitrocellulose." Applicant respectfully asserts that Youssefyeh does not teach or disclose the use of nitrocellulose as a film-forming carrier, and thus, does not disclose all the claim limitations of the presently claimed invention. The Examiner has

acknowledged as much, stating, "Youssefyeh [et al.] do not teach that the film-forming carrier is nitrocellulose." See Final Office Action at page 5, last but one paragraph.

The Examiner has cited Brandt to overcome the deficiencies of Youssefyeh. More specifically, according to the Examiner, "Brandt et al. ('216) teach fluid compositions that are coated onto the surface of a host animal and then dried to form a covering element, such as a transdermal bandage, patch or the like (col. 1, lines 7-2 1). The fluid compositions include film-forming polymeric components of cellulosic polymers such as nitrocellulose." See Final Office Action at page 5, final paragraph continuing to line 3 on page 6.

Applicant has shown by a Rule 132 Declaration that alkyl and hydroxyalkyl cellulose films are inferior to nitrocellulose film in transmitting an active component into the skin. This declaration has been discussed above and all arguments presented previously are again to be considered. Accordingly, the substitution of nitrocellulose of Brandt for those celluloses of Youssefyeh yields results totally unexpected by either of the applied references. The Rule 132 Declaration is applicable to claim 17 and claims dependent thereon.

Applicant again respectfully directs the Board of Patent Appeals and Interferences' attention to the Rule 131 Declaration of Joel Studin, submitted herewith (Appendix IX). As shown in the Rule 131 Declaration, Joel Studin directed Bryce Labs to prepare a composition for treating scars, eczema and psoriasis, containing a steroid (hydrocortisone acetate) in a film-forming carrier (flexible collodion), i.e., nitrocellulose, and apply the formulation to skin, prior to December 3, 1996. See Declaration at section 5. In as much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), prior to the earliest effective date of the Brandt reference (August 20, 1998), Brandt is no longer an effective reference against the invention as claimed.

As previously pointed out, the Rule 131 Declaration is also applicable to Youssefyeh. Accordingly, the combination of Youssefyeh and Brandt, et al. does not properly reject claims 17 and 18.

Independent claim 19

As previously pointed out, claim 19 has been amended to recite, "[a] composition for treating adverse skin conditions comprising a fluid, film-forming carrier and an active ingredient comprising a topically active steroid or, a silicone-gel or mixture thereof, said carrier capable of hardening to a tangible member, wherein said film-forming carrier is nitrocellulose."

Again, Applicant respectfully directs the Honorable Board's attention to the Rule 131 Declaration of Joel Studin, submitted herewith. As shown by the Rule 131 Declaration, Joel Studin invented the presently claimed invention prior to the earliest priority dates of Youssefyeh et al. (December 3, 1996) and Brandt et al. (August 20, 1998). According to the Declaration, Joel Studin directed Bryce Labs to prepare a composition for treating scars, eczema and psoriasis, containing a steroid (hydrocortisone acetate) in a film-forming carrier (flexible collodion), and apply the formulation to skin, prior to December 3, 1996. See Declaration at section 5. In as much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), prior to the earliest effective date of both Youssefyeh et al. (December 3, 1996) and the Brandt et al. reference (August 20, 1998), Youssefyeh and Brandt are no longer effective references against the invention as claimed.

Applicant has shown by a Rule 132 Declaration that alkyl and hydroxyalkyl cellulose films are inferior to nitrocellulose film in transmitting an active component into the skin. This declaration has been discussed above and all arguments presented previously are again to be considered. Accordingly, the substitution of nitrocellulose of Brandt for those celluloses of Youssefyeh yields

results totally unexpected by either of the applied references. The Rule 132 Declaration is applicable to independent claim 19 and claims dependent thereon.

(3) Rejection of Claims 22 and 24 under 35 U.S.C. § 103 (Re: Youssefyeh in view of Herb)

The Examiner has rejected claims 22 and 24 under 35 U.S.C. Section 103(a) as being unpatentable over Youssefyeh, et al. (U.S. 5,968,519, hereinafter "Youssefyeh") in view of Herb et al. (U.S. Pat. No. 5,534,246, hereinafter "Herb").

As previously pointed out hereinabove, independent claim 19, from which claims 22 and 24 depend, recites, "wherein said film-forming carrier is nitrocellulose." It is well established that to render a claimed invention obvious all the claim limitations must be taught or suggested by the prior art. As previously pointed out, Youssefyeh does not disclose the use of nitrocellulose as a film-forming carrier.

The Examiner cites Herb to overcome the deficiencies of Youssefyeh. More specifically, according to the Examiner, "Herb also teaches that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect of for adjusting the refractive index." See Final Office Action at page 6, final paragraph. However, like Youssefyeh, Herb does not disclose the use of nitrocellulose as a film-forming carrier, and thus, the combination of Youssefyeh with Herb does not disclose all the claim limitations of the presently claimed invention. Accordingly, it is believed that the rejection of the claims over the combination of Youssefyeh and Herb is improper and should be reversed.

(4) Rejection of Claims 17-21, 23 and 25 under 35 U.S.C. § 103 (Re: Mantelle '070 in view of Mantelle '363)

Claims 17-21, 23 and 25 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle, et al. (U.S. 5,446,070, hereinafter "Mantelle '070) in view of Mantelle, et al. (U.S. 6,562,363, hereinafter "Mantelle '363).

According to the Examiner, the '070 patent "teaches flexible, finite, bioadhesive compositions for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s), a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents ..." See Final Office Action at page 7, third paragraph. However, as the Examiner notes, "Mantelle [the '070 patent] does not teach that the film-forming carrier is nitrocellulose." See Final Office Action at page 8, third paragraph.

The Examiner has cited Mantelle '363 to overcome this deficiency. According to the Examiner, Mantelle '363 teaches "bioadhesive compositions in a flexible, finite form for topical application to skin or mucous membranes and methods for topical administration of active ingredients... [p]articularly suitable bioadhesive materials taught include cellulose materials such as nitrocellulose." See Final Office Action at page 8, fourth paragraph.

Applicant respectfully submits that Mantelle '363 is overcome on at least two grounds, the previously discussed Rule 131 and 132 Declarations. The Rule 131 Declaration clearly showed the Applicant reduced to practice a nitrocellulose film-forming carrier and an active ingredient as a composition and applied to skin prior to the effective filing date of Mantelle '363, and the Rule 132 Declaration clearly shows the nonequivalence of nitrocellulose as a film-forming carrier for a medicament such as a steroid. Criticisims of the Declarations have been addressed above. Reversal

of the final rejection over the combination of Mantelle '020 in view of Mantelle '363 is respectfully requested.

(5) Rejection of Claims 17-21, 23 and 25 under 35 U.S.C. § 103 (Re: Mantelle '070 in view of Brandt)

Claims 17-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070, "Mantelle '070) in view of Brandt et al. (U.S. Pat. No. 6,627,216, "Brandt").

Again, Mantelle '070 does not disclose the use of nitrocellulose as the film-forming carrier. The Examiner acknowledges as much, stating, "Mantelle [et al.] do not teach that the film-forming carrier is nitrocellulose." See Final Office Action at page 9, second paragraph.

The Examiner has cited Brandt to overcome this deficiency. More specifically, according to the Examiner, Brandt teaches the use of nitrocellulose as a film-forming carrier. However, Applicant has submitted herewith the Rule 131 Declaration of Joel Studin to overcome Brandt. As previously pointed out, in as much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), prior to the earliest effective date of the Brandt reference (August 20, 1998), Brandt is not an effective reference against the invention as claimed. As such, Applicant respectfully submits that Brandt cannot be properly cited against the present application.

In summary, the Examiner relies on the secondary reference to Brandt as teaching a nitrocellulose film-forming carrier. Applicant has further overcome the reference to Brandt by filing the above discussed Rule 132 Declaration. The Examiner's criticism of both the Rule 131 and Rule 132 Declarations are improper for the reasons stated above. The combination of Brandt and

Youssefyeh does not properly teach or suggest the applicant's claimed invention. Accordingly, it is believed that the rejection is improper and should be reversed.

(6) Rejection of Claims 22 and 24 under 35 U.S.C. § 103 (Re: Mantelle '070 in view of Herb)

Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070, hereinafter "Mantelle '070") in view of Herb et al. (U.S. Pat. No. 5,534,246, hereinafter "Herb").

As discussed above, Mantelle '070 patent does not disclose the use of nitrocellulose as the film-forming carrier or the use of phenyltrimethicone. The Examiner acknowledges as much, stating, "Mantelle [et al.] do not teach phenyltrimethicone." See Final Office Action at page 10, first paragraph.

The Examiner cites Herb to overcome the deficiencies of Mantelle et al. More specifically, according to the Examiner, "Herb et al. also teaches that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect of for adjusting the refractive index." See Final Office Action at page 10, second paragraph. However, like Mantelle '070, Herb does not disclose the use of nitrocellulose as a film-forming carrier, and thus, the combination of Mantelle '070 with Herb does not disclose all the claim limitations of the presently claimed invention.

As such, Applicant respectfully asserts that the combination of Mantelle '070 with Herb does not and cannot render claims 22 and 24 obvious. Reversal of this rejection is respectfully requested.

Still further, in rejecting claims 22 and 24 the Examiner cannot ignore the fact that they are dependent claims and therefore recite all the limitations of the corresponding independent claim.

MPEP 2111.01 states in part: "Finally, when evaluating the scope of a claim, every limitation in the claim must be considered. Claims 22 and 24 depend on independent claim 19, which recites in part the limitation: "wherein said film-forming carrier is nitrocellulose". Therefore, claims 22 and 24 also recite limitation: "wherein said film-forming carrier is nitrocellulose". Applicant respectfully points out that neither Mantelle '070 nor Herb mention the word "nitrocellulose" and neither reference teaches or suggests the use of nitrocellulose as a film-forming carrier as recited in independent claim 19 upon which claims 22 and 24 both depend. Accordingly, the Examiner's rejection based on Mantelle '070 in view of Herb is improper due to the failure of disclosing part of the claimed invention.

B. Conclusion

In conclusion, Applicant requests a reversal of the grounds of rejection maintained by the Examiner.

Respectfully submitted,

Date: August 6, 2009

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VIII. CLAIMS APPENDIX

17. A method of treating immunological skin disorders comprising applying onto an area of skin affected by said skin disorder a fluid, film-forming carrier having contained therein a steroid, and hardening the carrier into a tangible, membrane juxtaposed to said affected area, wherein said film-forming carrier is nitrocellulose.

18. The method of claim 17, wherein said skin disorder is eczema, psoriasis, or atopic dermatitis.

19. A composition for treating adverse skin conditions comprising a fluid, film-forming carrier and an active ingredient comprising a topically active steroid or, a silicone-gel or mixture thereof, said carrier capable of hardening to a tangible membrane, wherein said film-forming carrier is nitrocellulose.

20. The composition of claim 19, wherein said active ingredient is a topically active steroid comprising at least one corticosteroid or a pharmaceutically acceptable salt thereof.

21. The composition of claim 19, wherein said active ingredient is a silicone-gel.

22. The composition of claim 21, wherein said silicone-gel is phenyltrimethicone.

23. The composition of claim 19, wherein said active ingredient comprises a mixture of said steroid and silicone-gel.

24. The composition of claim 19, wherein said active ingredient further contains a vitamin.

25. The composition of claim 23, wherein said active ingredient comprises a mixture of said topical steroid, a silicone-gel, and optionally, vitamin E.

IX. EVIDENCE APPENDIX

This appendix includes case law and declarations that were relied upon or presented in the Appeal Brief. The following documents are included in this Appendix:

Declarations:

Rule 131 Declaration of Joel R. Studin (inventor) filed under 37 C.F.R. §1.131

Rule 132 Declaration of Joel R. Studin (inventor) filed under 37 C.F.R. §1.132

Exhibit:

Exhibit A (attached to the Rule 131 Declaration)

Exhibit A (attached to the Rule 132 Declaration)

X. RELATED PROCEEDINGS APPENDIX

NONE.